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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,357	07/23/2003	Ryland F. Young	HO-P01886US2	8574

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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,357	YOUNG ET AL.	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed June 4, 2007. Claims 13-50 and 52 are canceled. Claims 1.and 51 were amended.

Claims 1-12 and 51 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed December 1, 2006, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Objections

Claim 51 is objected to because of the following informalities: Claim 51 recites "the target polypeptide is or *murA*." There is no alternative listed, therefore the "or" needs to be removed. Appropriate correction is required.

Response to Arguments Concerning Claim Rejections – 35 USC § 102 (b)

Applicants' arguments filed on June 4, 2007 have been fully considered. The following grounds of traversal are presented:

Maratea et al do not teach the A_2 polypeptide.

Applicant's traversal has been fully considered and found to be persuasive in that Maratea et al do not teach the A_2 polypeptide. However, applicants'

amendment has necessitated the new grounds of rejection under 35 U.S.C. 103(a) recited below.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicants' arguments filed on June 4, 2007 have been fully considered. The following grounds of traversal are presented:

Maratea et al do not teach the A_2 polypeptide.

Neither Maratea et al nor Boyle et al teach the use of *murA*.

Applicant's traversal has been fully considered and found to be persuasive in that Maratea et al do not teach the A_2 polypeptide, and neither Maratea et al nor Boyle et al teach *murA*. However, applicants' amendment has necessitated the new grounds of rejection under 35 U.S.C. 103(a) recited below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maratea et al in view of Karnik et al.

Applicants claim a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-gene lysis polypeptide, wherein the lysis polypeptide is the A_2 polypeptide, comprising contacting bacteria with a lysis polypeptide; selecting for bacterial survivors of cell lysis caused by the lysis polypeptide that survive lysis by having the bacterial nucleic acid sequence that encodes a polypeptide making cells resistant to lysis by the lysis polypeptide; and mapping and isolating the candidate bacterial nucleic acid sequence, wherein the mapped sequence corresponds to the nucleic acid sequence which encodes the target polypeptide, involved in cell wall synthesis.

The claims further limit the invention to wherein contacting the bacteria with the lysis polypeptide comprises transforming bacteria with a vector comprising a nucleic acid sequence that encodes a single-gene lysis polypeptide, wherein its expression is induced, and the lysis polypeptide is mutated.

Maratea et al (Gene 40: 39-46, 1985, specifically materials & methods (b) and (c), pages 41, 44 and 45, and figures 1 and 2) teach a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-

gene lysis polypeptide. The single-gene lysis polypeptide is the *E* gene from bacteriophage ΦX174. Mapping of the candidate nucleic acid sequences that conferred resistance to the E polypeptide revealed mutants of the *slyD* gene, which is involved in cell wall synthesis. The wild type *E* gene and mutants of the *E* gene are inserted into vectors (see Table 1), as *E lacZ* fusions for expression and determination of β-gal activity. The *slyD* gene was characterized by mapping and testing of *slyD* mutants for sensitivity to the E *lacZ* fusions. Also, testing for the recessiveness of *slyD* was performed.

However, Marartea et al do not teach that the lysis polypeptide is the A_2 polypeptide.

Karnik et al (EMBO 2 (9): 1521-1526, 1983, specifically p. 1522) teach the lysis polypeptide, A_2.

The ordinary skilled artisan, desiring to use the A_2 polypeptide in a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-gene lysis polypeptide, would have been motivated to combine the teachings of Maratea et al teaching a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-gene lysis polypeptide comprising contacting bacteria with a lysis polypeptide; selecting for bacterial survivors of cell lysis caused by the lysis polypeptide that survive lysis by having the bacterial nucleic acid sequence that encodes a polypeptide making cells resistant to lysis by the lysis polypeptide; and mapping and isolating the candidate bacterial nucleic acid sequence, with the teachings of Karnik et al, teaching the A_2 polypeptide because the A_2 polypeptide is essential for infectivity.

It would have been obvious to one of ordinary skill in the art to use A_2 because Karnik et al teach that A_2 fulfills the lysis function of bacteriophage Qβ. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maratea et al in view of Karnik et al and in further view of Shimol et al.

Applicants claim determining the characteristics of the bacterial nucleic acid sequence by gel electrophoresis. They also insert the mapped bacterial nucleic acid sequence in an expression vector to produce a polypeptide, isolate the polypeptide and determine the characteristics of the polypeptide by electrophoresis.

Maratea et al and Karnik et al teach all of the limitations as described above. However, they do not teach determining the characteristics of the bacterial nucleic acid sequence by gel electrophoresis, inserting the mapped bacterial nucleic acid sequence in an expression vector to produce a polypeptide, isolating the polypeptide and determining the characteristics of the polypeptide by electrophoresis.

Shimol et al (J. Bac. 180(13): 3381-3387, 1998, specifically, pp. 3382-3383 and 3387) teach identifying a cell wall protein (Sed1p) required for lytic enzyme resistance. Sed1p is purified and characterized by amino acid sequencing, SDS PAGE, Western blotting and PNGase digestion. The SED1

gene was characterized by electrophoresis and then inserted into a plasmid, which was transformed into diploid cells. Sed1p was isolated by RPI treatment and further purified by reverse-phase chromatography. Amino acid sequencing was performed again.

The ordinary skilled artisan, desiring to determine the characteristics of the bacterial nucleic acid sequence and insert the bacterial nucleic acid sequence in an expression vector to produce a polypeptide, would have been motivated to combine the teachings of Maratea et al teaching a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-gene lysis polypeptide comprising contacting bacteria with a lysis polypeptide; selecting for bacterial survivors of cell lysis caused by the lysis polypeptide that survive lysis by having the bacterial nucleic acid sequence that encodes a polypeptide making cells resistant to lysis by the lysis polypeptide; and mapping and isolating the candidate bacterial nucleic acid sequence, with Karnik et al teaching the A_2 polypeptide, with the teachings of Shimol et al, teaching characterizing the SED1 gene and protein because Sed1p is required for lytic enzyme resistance. It would have been obvious to one of ordinary skill in the art to use SED1 for producing a protein that makes cells resistant to a lysis polypeptide because Shimol et al teach that Sed1p is a major structural wall protein and plays a role in cell defense mechanisms, including protection against cell lysis. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent

evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maratea et al in view of Karnik et al and in further view of Brown et al.

Applicants claim the bacterial nucleic acid sequence as *murA*.

Maratea et al and Karnik et al teach all of the limitations as described above. However, they do not teach the bacterial acid sequence as being *murA*.

Brown et al (J. Bac. 177(14): 4194-4197, 1995, specifically, Abstract and p. 4194) teach *murA* as encoding a cell wall synthesis protein.

The ordinary skilled artisan, desiring to use *murA*, would have been motivated to combine the teachings of Marate et al teaching a method of screening for a bacterial nucleic acid sequence that encodes a polypeptide for a single-gene lysis polypeptide comprising contacting bacteria with a lysis polypeptide; selecting for bacterial survivors of cell lysis caused by the lysis polypeptide that survive lysis by having the bacterial nucleic acid sequence that encodes a polypeptide making cells resistant to lysis by the lysis polypeptide; and mapping and isolating the candidate bacterial nucleic acid sequence, with Karnik et al teaching the A_2 polypeptide, and with the teachings of Brown et al, teaching *murA* as encoding a cell wall synthesis protein, because *murA* is an essential gene required for cell wall growth. It would have been obvious to one of ordinary skill in the art to use *murA* because Brown et al teach that *murA* prevent cells lysis. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be

considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy T. Vogel/
Primary Examiner, Art Unit 1636

Michele K Joike, Ph.D.
Examiner
Art Unit 1636